REMARKS/ARGUMENTS

Claims 1-6 and 24-26 are pending.

In the latest Office Action, all pending, previously allowed claims were rejected. Independent claims 1 and 24 were rejected for anticipation by Stone (5,306,311), independent claim 26 was rejected for anticipation by Cohen, even though it had previously been allowed over Cohen, and independent claim 25 was rejected for obviousness over Stone.

In regards to the Stone patent, the Office Action states that "Stone discloses using a wide variety of resorbable materials as the bioresorbable component" (Office Action, page 4) and viewed Stone as anticipating claim language relating to the removal of the joint surfaces to expose cancellous bone, selecting the implant, placing it between the joint surfaces, and using the joint until the implant has been resorbed.

Stone is primarily concerned with the material used for the prosthetic articular cartilage device 10 and how that device is manufactured. Column 5, lines 47-48, states that the device "includes a dry porous volume matrix 12 of biocompatible and at least partially resorbable fibers ...." (underlining added), and column 2, lines 52-54, states that the prosthetic device "is biomechanically able to withstand normal joint forces, and functions at those loads to protect the surrounding cartilage".

In column 3, lines 1-9, the Summary Of The Invention, Stone further teaches that the "prosthetic cartilage device also provides a scaffold for the regeneration of tissue having the physical characteristics of natural articular cartilage" and stresses that the "matrix is composed of biocompatible and bioresorbable fibers ...." (column 3, lines 22-23).

As the last quotation unambiguously explains, the matrix defined by the prosthetic implant is made of both biocompatible and bioresorbable fibers. Biocompatible fibers do not resorb, they are merely compatible with and therefore will not be rejected by natural tissue. The biocompatible fibers of Stone remain permanently in place, and they form a scaffold into which tissue having the physical characteristics of natural articular cartilage can grow.

Thus, Stone teaches to place a spacer between the joint surfaces made in part of a nonresorbable material, which then forms a support matrix into which tissue similar to natural cartilage can grow. The matrix does not resorb and remains permanently in place between the joint surfaces.

In contrast to Stone, the present invention is primarily concerned with resurfacing cancellous bone of non-weight bearing joints and is based on applicant's observation of what happens to such joints described in this application as follows:

> Therefore, my postulation is that the original surgery, removing the arthritic spurs and the uneven joint surface, left a raw bony surface normally covered by a blood clot or hematoma which then came in contact with the inert, smooth Silastic disc. The gradual fibroplasia of the blood clot appears to progress to fibrocartilage.
>
> Another important concept is the body's attempt to repair the joint surface with normal scar tissue. The basic cell of healing is called the fibroblast and will develop at any site of injury and is the transformation of a normal blood clot. The fibroblast will go through a series of histological microscopic changes called fibroplasia. <u>The fibroblast on a surface where there is constant motion will change and develop into an entity known as fibrocartilage.</u> This is white, smooth and looks very much like cartilage. (page 3, lines 22-38, underlining added)

The application continues to explain the present invention as follows:

> The present invention is based on the recognition that an implant that would stimulate and promote the formation of fibrocartilage could be used at a resected arthritic joint. The fibrocartilage would be a durable and competent joint surface for relief of pain, maintaining motion and adequate functional performance in the non-weight bearing, typically upper extremity, joints. .... The bioresorbable implant is placed between the resected joint surfaces and stimulates the formation of fibrocartilage as the bioresorbable implant is gradually dissipated and safely biologically resorbed by the body. (page 4, lines 10-22)

As the foregoing quotations from this application demonstrate, the present invention involves the formation of a layer of blood or hematoma on the resected bone surface

and placing a completely resorbable implant between the opposing joint surfaces so that there is constant motion between the implant and the blood or hematoma covering the bone. As described on page 3 of the present application, this constant motion will change and develop the fibroblast into fibrocartilage while the implant is being completely resorbed. Although fibrocartilage is not presently viewed as being useable in weight bearing joints, it covers resected bone surfaces with a layer of natural tissue, namely fibrocartilage, that is a "competent joint surface for relief of pain, maintaining motion and adequate functional performance in the non-weight bearing, typically upper extremity, joints" (application, page 4, lines 13-16).

Contrary to the present invention, Stone places an implant between the opposing surfaces which is not completely resorbable so that it can form a scaffold into which tissue having the physical characteristics of natural articular cartilage can grow. The biocompatible, nonresorbable components of the implant stay in place.

The independent claims have been amended to clearly distinguish them from Stone.

Independent claim 1 now recites in relevant parts "selecting an implant made of bioresorbable material only ...; placing the bioresorbable implant between the second joint surface and the cancellous bone surface so that the face [of the implant] is in slidable contact with the layer [of at least one of blood and hematoma] covering the cancellous bone surface ... while permitting unrestricted relative slidable motion between the face and the cancellous bone surface including the layer covering it; using the joint while allowing resorption of the implant and causing unrestricted slidable motions ... to stimulate the formation of fibroblast from the layer covering the cancellous bone surface so that the fibroblast can progress into fibrocartilage as the implant is resorbed ...."

Independent claim 24 is specifically limited to a "non-weight bearing body joint" and recites in relevant parts "placing an implant made of bioresorbable material only between the ... cancellous bone surface and the second surface ..., providing the implant with at least one face ... so that the implant can slidably move without restriction relative to the at least one degenerated cancellous bone surface while in contact with the layer of at least one of blood and

hematoma, allowing the face to slidably move relative to ... the layer ... without restriction to thereby stimulate the growth of fibroblast from the layer ... and the conversion of the fibroblast into fibrocartilage during the allowing step, and gradually resorbing the implant during the allowing step ...."

Independent claim 25, like claim 24, is specifically limited to treating a "non-weight bearing joint" and recites in relevant parts "removing at least a portion of the first joint surface to generate an exposed cancellous bone surface covered by a layer of at least one of blood and hematoma; placing an implant made of bioresorbable material only between and in contact with the exposed cancellous bone surface and the second joint surface ... using the joint and slidably moving the face [of the implant] relative to the exposed cancellous bone surface and the layer without restriction caused by the implant; allowing formation of fibroblast from the layer and of fibrocartilage from the fibroblast while using the joint as the implant is resorbed ...."

Finally, independent claim 26 recites in relevant parts "removing at least a portion of the first joint surface to expose a cancellous bone surface and covering the bone surface with a layer of at least one of blood and hematoma; ... selecting an implant made of bioresorbable material only ... using the joint while allowing complete resorption of the implant and permitting unrestricted relative slidable motion between the face and the cancellous bone surface and the layer; and allowing formation of fibroblast from the layer and of fibrocartilage from the fibroblast while using the joint as the implant is completely resorbed to replace the implant and maintain relative slidable motion between the bones along the formed fibrocartilage".

Stone neither teaches nor discloses or in any manner suggests to place a completely resorbable implant between the opposing bone surfaces, as is required by each independent claim 1 and 24-25. Stone's implant will never completely resorb, and portions of it will permanently remain in the joint. For this reason alone, the independent claims are not anticipated by Stone.

Each independent claim further requires permitting unrestricted slidable movement between the implant face and the opposing bone surface, including the blood or hematoma covering it, so that, as described on page 3, lines 35-37 of this application, the "fibroblast on a surface where there is constant motion will change and develop into an entity known as fibrocartilage". Since Stone's implant is in part made of biocompatible but nonresorbable material, it will never completely absorb, and portions of it will permanently remain in the joint, which would interfere with generating fibrocartilage in accordance with the present invention.

For this additional reason, the independent claims 1 and 24-26 are not anticipated by Stone.

In view thereof, applicant submits that independent claims 1 and 24 are not anticipated by and independent claim 25 is not obvious over Stone.

Claim 25 is not obvious over Stone because claim 25 has the same limitations discussed in the preceding paragraphs which render claims 1 and 24 patentable over Stone.

Independent claim 26 was rejected for anticipation by Cohen. Claim 26 recites amongst others "using the joint while allowing complete resorption of the implant, including unrestricted relative slidable motion between the face [of the implant] and the cancellous bone surface and the layer [of at least one of blood and hematoma] ...." As was extensively discussed in applicant's Amendment dated November 7, 2003 (and filed November 10, 2003), Cohen does not disclose or suggest to permit unrestricted movement between the opposing surfaces of the implant and the bone, which led to the retraction of the rejection of all but claim 26 over Cohen. For this reason alone, claim 26 is not anticipated by and is allowable over Cohen.

In addition, claim 26 includes the earlier discussed recitations requiring the implant to be completely resorbable and that the blood or hematoma is transformed into fibroblast and fibrocartilage. These limitations additionally patentably distinguish claim 26 over Cohen.

In view of the foregoing, applicant submits that claims 1, and therewith claims 2-6 which depend from claim 1, and claims 24-26 are neither anticipated by nor obvious over either Stone or Cohen.

In view of the foregoing, applicant submits that this application is in condition for allowance, and a corresponding notification at an early date is requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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